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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.     |
|---|-------------|----------------------|---------------------|----------------------|
| 10/020,436  | 12/18/2001  | Jonathan Clark       | 179-54              | 1671                 |
| 23117   | 7590        | 03/08/2005           | EXAMINER            |                      |
| NIXON & VANDERHYE, PC<br>1100 N GLEBE ROAD<br>8TH FLOOR<br>ARLINGTON, VA 22201-4714 |             |                      |                     | WESSENDORF, TERESA D |
| ART UNIT  |             | PAPER NUMBER         |                     |                      |
| 1639  |             |                      |                     |                      |

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |              |
|------------------------------|-----------------|--------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s) |
|                              | 10/020,436      | CLARK ET AL. |
| Examiner                     | Art Unit        |              |
| T. D. Wessendorf             | 1639            |              |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07 December 2004.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10, 12, 16 and 17 is/are pending in the application.

4a) Of the above claim(s) 4-9 and 16 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-3, 10, 12 and 17 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Status of Claims***

Claims 1-10, 12 and 16-17 are pending in the application.

Claims 4-9 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 11 and 13-15 have been cancelled.

Claims 1-3, 10, 12 and 17 are under examination.

***Withdrawn Objection and Rejection***

The objection to the oath/declaration and abstract is withdrawn with the submission of a new declaration and abstract. The 35 USC 112, first paragraph rejection for lack of enabling disclosure; 35 USC 112, second paragraph and 102 over Patel are withdrawn in view of the amendments to the claims.

***Essential Material***

The attempt to incorporate subject matter into this application by reference to WO 97/42216 is improper because it discloses the essential step of deconvolution of combinatorial libraries.

***Response to Arguments***

Applicants argue that while the orthogonal self-deconvoluting technique of WO 97/42216 is a convenient way of rapidly and graphically accessing results, it is by no means the

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only way of deconvoluting mixtures of compounds as recited in claim 1 c). Sheer brute computing power will do the job just as effectively albeit less elegantly. To restrict the invention to any single method of data manipulation would not be commensurate with Applicants' contribution to the art, which is the realization that kinase determinations can be run in stepped libraries of substrate mixtures without needing to separate unmodified from modified species, or their right to claim "the subject matter which the applicant regards as his invention." Because as explained above, the orthogonal deconvolution procedure is not an essential feature of the invention, simply citing their earlier-filed patent applications is believed to be adequate by Applicants to satisfy Section 112, first paragraph. But to assist a succinct appreciation of the claimed invention and to satisfy the Examiner's requirement, the relevant disclosure of WO 97/42216 has been added as Example 5 for inclusion in the specification. No new material has been added, although certain superfluous passages have been deleted and other adaptations have been made.

In response, there is nothing in the specification that recites for "sheer brute computing power" for deconvolution of the library. Rather, throughout the specification reference is made to WO 97/42216 deconvolution method, as claimed. Since this

process is included in the claim hence, it is considered to be a part of applicants' contribution to the art, as a whole. Merely citing the '216 World Patent does not satisfy the 112, first paragraph requirement of the law. Contrary to applicants' assertion incorporation of Example 5 that is not in the as-filed specification constitutes new matter. Furthermore, this is not applicants' earlier-filed application. See rejection below.

***Specification***

The amendment filed 12/7/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: e.g., page 4, paragraph 3, line 17 i.e., the inclusion specifically of Example 5. The as-filed specification does not recite the incorporation of the '216 WO Patent **and Example 5**. Thus, the incorporation of the foreign Patent to the specification is improper.

Applicant is required to cancel the new matter in the reply to this Office Action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 10, 12 and 17, as amended, are rejected under 35 U.S.C. 102(a) as being anticipated by Quibell et al (WO97/42216) for reasons set forth in the last Office action.

***Response to Arguments***

Applicants argue that the Examiner's contention that the "foreign priority filing date papers" cannot be relied upon is not understood. It is argued that the subject matter of this application must be described in the priority document. Here, the claims of priority document G89722818.3 are largely co-terminous with the claims as filed in the PCT application and under examination in the United States. Admittedly some exemplification was added to Int'l Patent Appln. No. PCT/US98/03259, but this was not "essential matter" nor was Applicants' concept of the invention changed. Even if arguendo the deconvolution process of WO 97/42216 was to be regarded as an essential element of the invention (which Applicants dispute), the priority document was filed with the text of WO 97/42216 as an appendix in order to provide continuity of disclosure. If this rejection is maintained, the Examiner is urged to substantiate what is meant by her objection and to indicate with particularity in what aspects the priority document does not satisfy Section 112 for the present claims.

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Furthermore, Applicants note that the present claims specifically include sub-libraries of mixtures where the modifiable residue is held fixed. This feature of the invention is not disclosed in Quibell et al.

In response, applicants fail to point out where in the foreign priority papers (UK 9722818.3), the instant claimed invention is supported. There is nothing in the '818 UK priority where the present claimed method is recited. See page 9 of the substitute PCT (PCT/GB 98/03259) application, (which is not in the '818 UK priority document). Furthermore, applicants' attention is drawn to Quibell at page 13, lines 5-25. Quibell discloses the sub-libraries of mixtures where the modifiable residue is held constant using the technique of Songyang et al. (See Songyang et al below).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

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art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 10, 12 and 17, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Songyang et al (Current Biology, ref. KR) in view of Patel et al (WO 96/23813) or Lam (Anti-cancer Drug Design).

Songyang et al discloses at page 973 col. 2 up to page 974, col. 2 a method of identifying a motif of a substrate molecule that binds to an active site of a tyrosine kinase that phosphorylates tyr or ser with a consensus peptide protein kinase substrate as shown at page 974, col. 1. A degenerate library of peptides with a phosphoacceptor such as Tyr or Ser/thr flanked by amino acids on each side is synthesized. The number of degenerate residues on each side of the phosphorylation site is four (positions -1, -2, -3, -4, +1, +2, +3, +4) relative to the phosphorylated residue. The library consists of peptides having a length of nine amino acids. The library is then phosphorylated by the protein kinase. See further the Materials and Methods section at page 980 up to page 981. Songyang does not disclose a deconvolution step of the degenerate library as recited in step ② as claimed. However, Patel discloses at page 114, Example 44 a deconvolution of peptide library. Patel further teaches that the libraries (n=1)

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were mixed in unequal amounts, thus aiding in the identification of the active fraction in mixtures (of up to four bead-bound peptides). Lam at page 150 up to page 151 discloses the different types of deconvolution method including the one applied to a positional scanning approach. Lam said that this method is a one-step approach and multi-step synthesis and analysis is not needed. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a deconvolution step in the method of Songyang as taught by Patel or Lam. Patel discloses that the use of deconvolution results in discriminating deconvolution samples i.e., active fraction in a mixture. Lam also teaches that deconvolution method as used in positional scanning is a one-step approach that does not require multi-step synthesis and analysis. Thus, one would have been motivated to use a deconvolution step in the method of Songyang for the advantages taught by either Patel or Lam. Deconvultion step is normally applied to a combinatorial library containing millions of compounds, as taught by Lam.

No claim is allowed.

**Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 4-9 and 16 drawn to a non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*T. D. W.*  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw  
March 4, 2005